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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,802	03/16/2000	Jagdish Parasrampuria	4600-0131.30	1577

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
1616	12

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/526,802</b>	Applicant(s) <b>Parasampuria et al</b>	
	Examiner <b>Sabiha Qazi</b>	Art Unit <b>1616</b>	
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --			
<b>Period for Reply</b>			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jan 8, 2002</u>			
2a) <input type="checkbox"/> This action is <b>FINAL</b> .		2b) <input checked="" type="checkbox"/> This action is non-final.	
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-35</u> is/are pending in the application.			
4a) Of the above, claim(s) <u>9 and 11-35</u> is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input checked="" type="checkbox"/> Claim(s) <u>1-8 and 10</u> is/are rejected.			
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.			
8) <input checked="" type="checkbox"/> Claims <u>9 and 11-35</u> are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. § 119</b>			
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).			
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:			
1. <input type="checkbox"/> Certified copies of the priority documents have been received.			
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.			
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).			
*See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).			
<b>Attachment(s)</b>			
15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)		18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____	
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>4</u>		20) <input type="checkbox"/> Other: _____	

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### **First Office Action on Merits**

*Instant invention is drawn to formulations and method of use of form I polymorph and form II polymorph of dihydroepiandrosterone (DHEA).*

Claims 1-35 are pending.

No claim is allowed.

Claims 1-8 and 10 are examined, others are withdrawn from consideration as non elected invention.

Response and election of group I, claims 1-4 with traverse filed on 1/8/02 is hereby acknowledged. The traversal is on the grounds that restriction between groups I-V should be withdrawn because claims 1-17 can be examined together without serious burden. On Applicant's request Examiner had reconsidered the restriction requirement and combined claims 1-4 of group I and claims 5-8 and 10 from group II for examination. Claims 1-4 are drawn to pharmaceutical formulations of DHEA and claims 5-8 and 9 are drawn to method for preparing formulations, others are drawn to different formulations and methods for treatment of systemic lupus erythematosus, to prevention or reduction of loss of bone density, and treatment of chronic fatigue syndrome or fibromyalgia.

The inventions are distinct, claims are drawn to different formulation, method of making and method of use, each of them require a separate database and other search. It would be a burden on the Examiner to search all the invention in this application. Restriction is considered proper for the reasons set forth in our previous office action and is made FINAL.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales et al. (US 5,407,927) and Loria et al. (US 5,077,284) in combination of Chang et al. (DN 123:265915, HCPLUS, abstract of J. Pharm. Sci. (1995), 84(10), 1169-79). These references teach formulations, methods and polymorphic forms of DHEA which embraces Applicant's claimed invention. See the entire documents especially lines 37-62, col. 1; lines 4-10 and lines 59-66, col. 12 in US 5,077,284 and lines 59-68, col. 2; lines 25-58, col. 3 and table 2 in col. 7 in US 5,407,927. These references teach the formulation of DHEA for various method of treatments. Chang et al. teaches solid state crystallization of DHEA and its polymorph (forms I-III). Furthermore, it discloses that form I is more stable than others. See abstract in the article AQ in form 1449.

Instant claims differ from the reference in claiming formulations and method of preparation of specific polymorphic form I of DHEA.

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It would have been obvious to one skilled in the art at the time when instant invention was made, to be motivated to prepare additional beneficial preparations and formulations of DHEA by using any polymorphic form of this compound especially form I and would expect the same results because when the compositions of the compound would be prepared, it would be the same after dissolving in the solvent, no matter what polymorphic form exists in the solid state. Motivation is to prepare formulations, of DHEA form I polymorph because form I is taught to be more stable, for the treatment of systemic lupus erythematosus, to prevention or reduction of loss of bone density, and treatment of chronic fatigue syndrome or fibromyalgia. One would expect same properties with the polymorphic form I of DHEA formulation. Different polymorphic forms are not patentable over each other in absence of unexpected properties.

It had been held that by changing the form, purity or other characteristics of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art. *In re Cofer*, 53 CCPA (1966) 830, 835, 354 F2d 664, 668, 148 USPQ 268, 271.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

***Telephone Inquiry Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

2/9/02



SABIHA QAZI, PH.D  
PRIMARY EXAMINER